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COHEN, PONTANI, LIEBERMAN & PAVANE
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
FERNANDEZ, KATHERINE L	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,585	Applicant(s) HAHL, MARKUS	
	Examiner KATHERINE L. FERNANDEZ	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _17 December 2007_.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _39-76_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _39-76_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _17 December 2007_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 39-54, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. (US Patent No. 6,348,694) in view of Anderson et al. (US Patent No. 6,436,127).

With regards to claims 39 and 43-48, Gershteyn et al. disclose a device for determining an allowable UV exposure time or allowable UV radiation dose for human skin, comprising: a UV emitter for emitting UV radiation on the skin (column 12, lines 28-47; column 11, lines 17-52; column 12, lines 6-19; column 8, lines 51-54); a UV sensor for receiving UV radiation reflected by the skin (column 13, lines 6-27); an evaluation unit coupled to the UV emitter and the UV sensor for determining UV radiation absorption of the skin based on the UV radiation emitted on the skin by the UV emitter and the UV radiation received by the UV sensor (column 14, lines 17-41; column 19, line 47-column 20, line 6). Further, with regards to instant claims 44-48, Gershteyn et al. disclose that the housing (90) has an application surface (22) for placement on the skin (24) (Figure 6). Further, Gershteyn et al. disclose that optical guides, such as fibers, planar waveguides, or waveguides having various other geometries may be selected as suitable radiation paths for their invention (column 11, lines 4-16). Further,

they disclose that the radiation sensors having planes of incidence at various orientations are employed to detect ambient radiation at a number of incidence angles (column 19, lines 18-28). The sensors can be arranged such that radiation from several directions may be detected from various locations proximate to the skin (column 19, lines 18-46). However, Gershteyn et al. do not specifically disclose that the UV radiation received by the UV sensor is diffusely reflected by the skin. Further, they do not specifically disclose that the UV emitter and the UV sensor are disposed at an angle relative to each other so that a reflection of a ray on the optical axes of the UV emitter and the UV sensor occurs at a depth of penetration sufficient to measure diffuse reflection in a layer of skin, wherein the depth of penetration can be varied, wherein the optical axes of the UV emitter and the UV sensor span an angle of approximately 70-110 degrees, wherein the angle of the optical axes can be adjusted to vary the depth of penetration, or wherein each of the UV emitter and the UV sensor is disposed at a distance above the application surface, and the distance can be adjusted to vary the depth of penetration.

Anderson et al. disclose methods and systems for treating inflammatory, proliferative skin disorders with ultraviolet phototherapy (column 2, lines 37-39). Their system includes an illumination source configured to irradiate the patient's skin, a detector configured to receive optical radiation emitted from selected areas of the patient's skin in response to the irradiation from the illumination source and to generate a signal relating to the radiation received from each of the selected areas, and an analyzer connected to the detector, wherein the analyzer compares the signals from the

selected areas to at least one threshold parameter and designates selected areas having measured signals above the threshold parameters as affected areas (column 3, lines 49-64). They disclose that their detector can measure diffuse reflectance and the analyzer can compare the signals relating to the diffuse reflectance to the at least one threshold parameter to designate the affected areas (column 3, line 65-column 4, line 4). Reflectance measurements are made using a polarized light source, and they disclose that diffuse reflectance is preferred as a diagnostic of psoriasis since the diffuse component includes information about reflectance from within the skin tissue (column 7, lines 51-67). Anderson et al. disclose that their system is arranged such that a scanning mirror and a dichroic mirror direct the beams to the patient's skin, and a scanning controller adjusts the vertical angle of the scanning mirror, thereby directing the beam to different vertical positions of the patient's skin. Although they do not specifically disclose that the optical axes of the UV emitter and the UV sensor span an angle of approximately 70-110 degrees, they do disclose that the vertical angle of the scanning mirror can be adjusted, and therefore it would have been within the skill of one of ordinary skill in the art to adjust the optical axes angle to 70-110 degrees in order to achieve the desired depth of penetration. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Gershteyn et al. to have the UV sensor receive UV radiation diffusely reflected by the skin and include the limitations of instant claims 44-48, as taught by Anderson et al., in order to collect information about reflectance from within the skin tissue at a desired penetration depth (column 7, lines 63-67).

With regards to claims 40-42, Gershteyn et al. disclose that any wavelength outside the absorption spectrum of sunscreen can be selected for use as a radiation wavelength (column 11, lines 46-52). Further, they disclose that many sunscreens are designed to have an absorption spectrum similar to that of the UV-B ultraviolet wavelength range (i.e. 300 nm to 320 nm) (column 11, lines 30-33). Therefore, the UV emitter can emit UV radiation in any wavelength outside the range of 300 nm to 320 nm, and therefore UV radiation can fall within a range for which the skin has an absorption coefficient greater than or equal to a scattering coefficient, have a wavelength smaller than the diameter of a skin cell nucleus, and have a wavelength of approximately 345 nm to 355 nm.

With regards to claims 49-51 and 65, Gershtyn et al. disclose that their apparatus includes a processor unit that is coupled to the evaluation unit (column 20, lines 17-53). They disclose that the processor may calculate a sum of the signals representing the total exposure level of the skin to the radiation, as well as calculate and provide information relating to the directionality of radiation impinging on the apparatus (column 20, line 42 through column 21, line 30). A peak exposure signal can be passed to the processor (column 21, lines 6-17). The processor may also include various memories (RAM,ROM) (column 21, lines 18-29).

With regards to claims 52-53, Gershtyn et al. disclose that their apparatus comprises an interface (86, 102, processor with a central processing unit and memory; user-interface) for storing and retrieving data (Figure 7, column 21, lines 39-48). Further, they disclose that the interface can be used to operate a UV radiation source

(i.e pressing the “START” button on the user interface) (column 21, lines 30-38; column 22, lines 14-27).

With regards to claim 54, as can be seen from Figures 5-6, the housing (90) has two pairs of UV sensors (70A, 70B, 70C, and 70D), with the two UV sensors in each pair oppositely disposed, and the two pairs of UV sensors are disposed at an angle of approximately 90 degrees relative to each other (Figures 5-6).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 55-59 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Anderson as applied to claim 54 above, and further in view of Benaron et al. (US Patent No. 5,807,261).

As discussed above, the combined references meet the limitations of claim 54. Further, Gershteyn et al. disclose that the sensors can detect ultraviolet radiation (i.e. erythema-effective spectrum) (column 11, lines 40-60). With regards to claim 64, Gershtyn et al. disclose that their apparatus comprises an interface (86, 102, processor with a central processing unit and memory; user-interface) for storing and retrieving data (i.e. databank for storing data received by the sensor) (Figure 7, column 21, lines 39-48). However, they do not specifically disclose that their device further comprises four optical waveguides, each of the optical waveguides having a free end, and the two

pairs of UV sensors are formed by the free ends of the optical waveguides. They also do not disclose that the free ends of the optical waveguides has a filter operable to cause a short-wave component of a diffusely reflected UV radiation to be reflected to a greater extent than a long-wave component of the diffusedly reflected UV radiation, nor that each of the optical waveguides is connected to a common UV sensor. Benaron et al. disclose sensors for in vivo measurements of body tissues (column 1, lines 25-29). They disclose an embodiment of their invention that provides a tissue interrogating tool including a penetrating device with an optical sensor for use in determining whether or not the penetrating device has penetrated to the desired body cavity (column 20, lines 28-41). They disclose that the optical sensor may have a multiplicity of optical components at the distal end of the puncturing tool for emitting and launching light and coupling and detecting light to provide a signal corresponding to the spectral characteristics of the tissue presented to the tool (column 20, lines 33-41). The light detecting window may be one optical waveguide adapted to receive all light sensed, or alternately, the light detecting window may have separate optical waveguides for receiving the light (i.e. sensors comprised of optical waveguides) (column 21, lines 12-26). Further, they disclose that the sensed light signals are can be demultiplexed by time using frequency selective filters that will chop the sensed light into frequency selective signals. At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the device of Gershteyn et al. in view of Anderson to include the limitations listed above, as taught by Benaron et al., in order to receive all light sensed and to chop the sensed light into frequency selective segments in order to

acquire the desired spectral characteristics (column 21, lines 12-26, column 26, lines 57-67).

5. Claim 60 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Anderson et al. as applied to claim 54 above and further in view of Lenderink et al. (US Patent No. 6,736,832).

As discussed above, Gershteyn et al. and Anderson et al. meet the limitations of claim 54. However, they do not specifically disclose that the distance between the two UV sensors of one pair of the two pairs of UV sensors is approximately equal to a height of a human body lying on a tanning bed. Lenderink et al. disclose a method comprising the steps of determining a quantity related to a person's personal minimum erythema dose and using the quantity as an input for a tanning-related device, influencing its operation (column 1, lines 8-13). They disclose that the tanning is induced by irradiation with ultraviolet light (column 1, lines 14-15). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Gershteyn et al. in view of Anderson et al. to have the UV sensors be approximately equal to a height of a human body lying on a tanning bed, as taught by Lenderink et al., in order to allow a person in a tanning bed to determine when they have been exposed to the radiation for too long and thus avoid radiation damage (column 1, lines 14-60).

6. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Anderson et al. as applied to claim 54 above and further in view of Lipman et al. (US Pub. No. 2002/0052562).

As discussed above, Gershteyn et al. and Anderson et al. meet the limitations of claim 54. However, Gershteyn et al. do not disclose that their device further comprises a distance measuring instrument for maintaining a predetermined distance between a UV radiation source and skin. Lipman et al. discloses neurological diagnostic tools including method and devices for monitoring and managing patient pain (pg. 1, paragraph [0002]). They disclose one embodiment of their system that includes a hand held fixture to hold a heat source assembly that includes two projector bulbs to generate the heat beam (pg. 8, paragraph [0086]). Also included in their invention is a distance measuring device (pg. 8, paragraph [0086]). The device provides a display indicator to tell the operator how to adjust the hand held unit (i.e. toward or away from the skin) in order to keep it at the proper distance (pg. 8, paragraph [0086]). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included a distance measuring instrument in the invention of Gershteyn et al in view of Anderson et al., as taught by Lipman et al., in order to tell the operator how to adjust the device in order to maintain the device at the proper distance (pg. 8, paragraph [0086]).

7. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gershteyn et al. in view of Anderson et al. as applied to claim 39 above, and further in view of Shi (US Patent No. 5,107,123).

Gershteyn et al. do not disclose that their device further comprises a temperature sensor. Further, they do not disclose that the temperature sensor is coupled to an evaluation unit and is operable to initiate a UV radiation absorption determination of the skin when an optimum bulb wall temperature of a UV radiation source to be measured

in a tanning bed is reached. Shi discloses an ultraviolet radiation measuring device for measuring ultraviolet radiation in a selected environment. They disclose that their invention includes a temperature sensor located in close proximity with an optical-electrical signal converter (column 6, lines 62-63). The temperature sensor monitors the ambient temperature and provides electrical signals indicative of the monitored temperature (column 6, lines 62-66). The temperature is displayed and used for further processing of the UV intensity signal (column 6, line 62 through column 7, line 4). A processor takes a digital ultraviolet intensity signal and digital temperature signal and generated display signals representative of the instantaneous radiation levels present in the area sensed by the device (i.e. temperature sensor is coupled to a processor, which serves as an evaluation unit)(column 7, lines 26-32). The processor also integrates the measured levels over time to calculate an accumulated ultraviolet radiation value used to obtain a prescribed radiation dose (column 7, lines 32-36). At the time of the invention, it would have been obvious to one of ordinary skill in the art to have included the limitations discussed above in the invention of Gershteyn et al. in view of Anderson et al., in order to generate an ultraviolet intensity signal which is independent of ambient temperature, as taught by Shi (column 5, lines 56-65).

8. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gershtyn et al. in view of Anderson et al. as applied to claim 65 above and further in view of Wulf (US Patent No. 4,882,598).

As discussed above, Gershtyn et al. in view of Anderson et al. meet the limitations of claim 65. However, they do not disclose that when the maximum UV

exposure time or UV radiation is reached, the UV radiation source is shut off. Wulf et al. disclose a method and an apparatus for determining an individual's ability to stand exposure to ultraviolet radiation prior to causing a skin reaction, or for determining an individual's ability to become tanned by exposure to ultraviolet radiation (abstract). They disclose that their invention determines when an individual should not expose his or her body to ultraviolet radiation (i.e when maximum UV exposure time or UV radiation is reached) and if the computer has determined that the individual is erythrodermic or erythematous, the power to the tubes or bulbs are cut off (i.e. radiation source is shut off) (column 18, line 41 through column 19, line 16). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Gershtyn et al. in view of Anderson et al. to have the UV radiation source shut off when the maximum UV exposure time or UV radiation is reached, as taught by Wulf et al., in order to prevent radiation damage.

9. Claims 67-69, 71-72 and 75-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Wulf et al.

Anderson et al. disclose a method of determining an allowable UV exposure time or allowable UV radiation dose for human skin comprising: determining absorption of erythemally-effective UV radiation in a layer of the skin, at different sites and depth of skin, that has developed hyperkeratosis based on a degree of diffuse reflection of UV radiation in the layer of skin, the depth of the determination being adjusted for a determination in a specific skin layer, wherein the method is used during a UV irradiation treatment of a human being, and wherein the method is carried out by using

a device comprising a UV emitter for emitting UV radiation on the skin, a UV sensor for receiving UV radition diffusely reflected by the skin, and an evaluation unit coupled to the UV emitter and the UV sensor for determining UV radiation absorption of the skin based on the UV radiation emitted on the skin by the UV emitter and the UV radiation received by the UV sensor (column 7, line 51-column 8, line 21; column 8, line 66-column 10, line 65). The UV radiation is carried out by means of direct UV irradiation (i.e. 355 nm) and can be carried out by means of fluorescence photometry (column 9, lines 23-51; column 17, lines 6-9). However, they do not disclose that a UV radiation threshold value is assigned to the determination of UV radiation absorption of the skin. Wulf et al. disclose a method and an apparatus for determining an individual’s ability to stand exposure to ultraviolet radiation prior to causing a skin reaction, or for determining an individual’s ability to become tanned by exposure to ultraviolet radiation (abstract).They disclose that a logarithmic representation of the coefficient of reflection is computed to serve as a measure representing an individual’s ability to become tanned by exposure to ultraviolet radiation (column 2, lines 12-33). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Anderson et al. to assign a UV radiation threshold value to the determination of UV radiation absorption of the skin, as taught by Wulf et al., in order to provide an indicator of an individual's ability to stand exposure to ultraviolet radiation prior to causing a skin reaction.

10. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Wulf as applied to claim 67 above, and further in view of Kaminski et al. (US Patent No. 5,640,957).

As discussed above, the above combined references meet the limitations of claim 67. However, they do not specifically disclose that a mean value of a plurality of determinations of UV radiation absorption of the skin is taken, and a UV radiation threshold value is assigned to the mean value. Kaminski et al. disclose an apparatus for evaluating the effectiveness and determining the appropriate sun protection factor (SPF) rating of sunscreens (column 1, lines 8-12). They disclose that their method includes computing the average sun protection factor for the desired range (i.e. UVA or UVB) or the combined entire ultraviolet range (column 4, lines 49-58). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Anderson et al. in view of Wulf to calculate a mean value of a plurality of determinations of UV radiation absorption of the skin, and assign a UV radiation threshold value to the mean value, as taught by Kaminski et al., in order to provide a reliable indicator (column 5, lines 2-6).

11. Claims 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. in view of Wulf as applied to claim 67 above, and further in view of Gershteyn et al..

As discussed above, the above combined references meet the limitations of claim 67. However, they do not specifically disclose that a maximum UV exposure time or UV radiation dose is determined from the threshold value and stored data of a UV

radiation source, nor does he disclose that the stored data are data derived from a measurement of the UV radiation source. Gershtyn et al. disclose that their apparatus comprises includes a processor with a central processing unit and memory for storing and retrieving data (Figure 7, column 21, lines 39-48). Further, they disclose that their apparatus may store an initial calculation (i.e. data derived from a measurement of the UV radiation source) in memory so that the calculation may be compared to the calculation measured at later times (column 21, lines 39-48). Further, they disclose that their apparatus can provide a measure of cumulative tan (column 21, lines 49-61). At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of Anderson et al. in view of Wulf to have the maximum UV exposure time or UV radiation dose be determined from the threshold value and stored data of a UV radiation source, as taught by Gershtyn et al., in order to provide a cumulative indicator, as taught by Gershtyn et al. (column 21, lines 30-61).

Response to Arguments

12. Applicant's arguments with respect to claims 39-76 have been considered but are moot in view of the new ground(s) of rejection.

With regards to the Gershteyn reference, applicant argues that Gershteyn teaches "that only the second radiation is used to determine an indication of how susceptible the skin is to damage by harmful radiation, and that the second radiation is in the visible light range of 400 nm-760 nm". Examiner respectfully disagrees. Gershteyn does disclose, as an example, that the second radiation may include one or more wavelengths in a range of from approximately 400 nm-760 nm; however, they

further disclose that this wavelength range is provided merely for illustrative purposes, as their invention is not limited to use with any particular wavelength (column 12, lines 6-19). They further disclose that any wavelength range outside the absorption spectrum of a sunscreen can be selected for the second radiation. Since many sunscreens have an absoprtion spectrum similar to that of UV-B ultraviolet wavlength range (300-320 nm), it is possible for the second radiation to fall in the ultraviolet range outside of 300-320 nm.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE L. FERNANDEZ whose telephone number is (571)272-1957. The examiner can normally be reached on 8:30-5, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768